**APPROVED MEETING MINUTES**
**California Department of Health Services, Human Stem Cell Research Advisory Committee**
**February 24, 2006**
**Children's Hospital Oakland Research Institute**
**1:00 PM – 5:00 PM**

**Attendance:**

**California Department of Health Services, Human Stem Cell Research Advisory Committee Members**
Elizabeth Blackburn, Ph.D. (by phone for selected portions of the meeting)
Samuel Cheshier, M.D., Ph.D.
Rabbi Elliot Dorff, Ph.D.
Fred Gage, Ph.D. (by phone for selected portions of the meeting)
Henry Greely, J.D.
Bertram Lubin, M.D.
David Magnus, Ph.D.
Otoniel Martinez-Maza, Ph.D.
Margaret McLean, Ph.D. (by phone for selected portions of the meeting)
Radika Rao, J.D.
Gregory Stock, Ph.D., M.B.A
Irving Weissman, M.D.

**CDHS**
Shabbir Ahmad, Manager, Human Stem Cell Research Unit, CDHS
Cindy Chambers, Human Stem Cell Research Unit, CDHS
Stefanie Lee, CDHS Staff
Patricia Rodriguez, CDHS Legal Counsel

**Invited Guest**
Alta Charo, J.D.

**Members of the Public**
Wanda Carell, University of California San Francisco, College of Law
Susan Fogel, Coordinator, Pro-Choice Alliance for Responsible Research (by phone)
Kurt Franken, California Institute for Regenerative Medicine (CIRM)
Jacquelyn Garman, Children's Hospital & Research Center Oakland (CHRCO)
Lynne Hollyer, UC Berkeley, Office of Intellectual Property and Industry Research Alliances (IPIRA)
Sam Leticia, Stanford University, Neurological Surgery
Geoffrey Lomax, Senior Officer, California Institute for Regenerative Medicine (CIRM)
Lily Mirels, UC Berkeley
Robert Price, Associate Vice Chancellor for Research, UC Berkeley
Jesse Reynolds, Center for Genetics and Society
Peter L. Schuerman, Director, Office of Intellectual Property and Industry Research Alliances (IPIRA), UC Berkeley
John Simpson, Stem Cell Project Director, The Foundation for Taxpayer and Consumer Rights (by phone)
Shannon Smith-Crowley, ACOG, American Society for Reproductive Medicine (by phone)
Charis M. Thompson, UC Berkeley
Nicole Vazquez, Senator Ortiz's Office, Senate Health Committee (by phone)

**Agenda Item #1: Welcome, Shabbir Ahmad**

**Agenda Item #2: Introduction to the CDHS HSCR Advisory Committee, Shabbir Ahmad & Cindy Chambers**

The legislative history of California Stem Cell Research was presented with specific attention to the differences between SB 322 and Proposition 71.

SB 322 (2003) charged the California Department of Health Services (CDHS) with five primary tasks:

1. Establish a Human Stem Cell Research Advisory Committee consisting of 13 members representing professional specialties as specified in the statute.
2. Develop statewide standards for human embryonic stem cell research.
3. Collect mandated progress reports from all Institutional Review Boards (IRBs) in California regarding the status of approved projects and proposals involving stem cell research.
4. Review all IRB reports, and revise guidelines as necessary.
5. Report annually to the Legislature on human embryonic stem cell research activity in California.

Proposition 71, the California Stem Cell Research and Cures Act, enacted in November of 2004, authorized $3 billion in state general obligation bonds over 10 years to provide funding for stem cell research and research facilities in California. Proposition 71, which established the California Institute for Regenerative Medicine (CIRM) included language that specifically exempted the Institute (CIRM) and its grantees from the provisions of SB 322 as well as any other current or future state laws or regulations.

Consequently, the guidelines created by the HSCR Advisory Committee in accordance with SB 322 will apply only to non-CIRM-funded (i.e. non Proposition 71) human embryonic stem cell research in California. Additionally it was noted that although the HSCR Advisory Committee will be providing expert advice in developing the CDHS statewide guidelines for human embryonic stem cell research, CDHS will have the final approval of any standards ultimately adopted.

To view Shabbir Ahmad and Cindy Chambers presentation, see this URL:
http://www.mch.dhs.ca.gov/documents/ppt/HSCR_Presentation_2-24-06.ppt

**Agenda Item # 3: Proposed Conflict of Interest Policies**

Conflict of Interest Policies were unanimously approved.
To view the Conflict of Interest Policies, see this URL:
http://www.mch.dhs.ca.gov/documents/pdf/HSCR-Advisory-Committee-Conflict-of-Interest-Policy.pdf
http://www.mch.dhs.ca.gov/documents/pdf/HSCR-Advisory-Committee-Conflict-of-Interest-Disclosure.pdf

**Agenda Item #4: Proposed Committee Bylaws**

Committee Bylaws were unanimously approved.
To view the Committee Bylaws, see this URL:
http://www.mch.dhs.ca.gov/documents/pdf/HSCR-Advisory-Committee-Bylaws.pdf

**Agenda Item #5: Vote on Committee Chair and Vice Chair**

The HSCR Advisory Committee elected Professor Henry Greely the Committee Chair and Dr. Bertram H. Lubin the Committee Vice Chair. As the new Chair, Professor Greely presided over the remainder of the meeting.

As Dr. Dorff was unable to stay for the entire meeting, he requested he be granted the floor to state his comments and concerns regarding what he felt to be some of the issues surrounding the creation of guidelines for human embryonic stem cell research. Professor Greely granted Dr. Dorff's request.

Dr. Dorff had four issues he wanted to discuss.

1. How realistic is it to expect women to donate eggs to research free of charge, especially in light of current IVF practices enticing young college women with advertisements promising payment of thousands of dollars?
2. How will CIRM grantees demonstrate that the donation of oocytes for research shall not compromise the optimal reproductive success of the woman in fertility treatment?
3. How is it relevant that an oocyte donor be made aware of the method in which stem cells will be derived from her oocyte(s) (i.e. via fertilization, SCNT, pathogenesis or some of other method)?
4. Added to the CIRM and SB 322 guidelines should be a statement that neither consenting nor refusing to donate embryos for research will affect the quality of any future care provided to potential donors as well as a provision allowing clinical personnel who have a conscientious objection to human embryonic stem cell research to abstain from participation (as was made in the NAS guidelines).

**Agenda Item #6: Presentation: National Academy of Sciences (NAS) Guidelines and California Institute for Regenerative Medicine (CIRM) Regulations (Alta Charo, J.D.)**

Professor Alta Charo outlined what she would be covering during her presentation starting with a discussion of the origins of some legal questions, followed by a few highlights from the National Academy of Science's report as well as the proposed CIRM regulations, and finally, leaving time at the end for discussion.

Professor Charo first discussed a number of federal regulations that indirectly address stem cell research generally, and human embryonic stem cell research specifically.

- The Food and Drug Administration regulates tissue transplantation. To the extent that stem cell research is purely a laboratory exercise the FDA is not really involved. If, however stem cell lines are used to create transplantable tissue, the FDA would then step in due to its interest in the prevention of the spread of infectious disease.
- If tissue derived from stem cell research is to be transplanted into a human, researchers will have to have followed the FDA's rule on screening the original donor for infectious diseases.
- Researchers will also have to retain donor identity of stem cell lines in the event that future testing or screening for new infections or genetic disorders that may have emerged since the time of donation is additionally required, effectively preventing anonymization.
- Retaining donor information with stem cell lines will also require compliance with HIPPA privacy laws.

Professor Charo then discussed the creation of the guidelines created by the National Academy of Sciences (NAS) for embryonic stem cell research which were written to fill in some of the gaps in federal laws and regulations that existed on general topics such as FDA regulation, animal welfare, and genetic engineering. The NAS guidelines, she stated were intended to increase public confidence in the management of embryonic stem cell research, as well as facilitate collaboration among laboratories by harmonizing core ethical standards. Professor Charo highlighted the following NAS recommendations:

- The creation of the Embryonic Stem Cell Research Oversight (ESCRO) Committees separate from the IRBs that already exist.
- The expansion of the IRB's jurisdiction with regard to human subject's research to include oversight of the donation of human embryonic tissue.
- Substantive limits on certain forms of laboratory research.
- That neither sperm nor oocyte donors should be paid for donations to be used for stem cell research.

Professor Charo then gave an overview of the proposed California Institute for Regenerative Medicine (CIRM) regulations.

- The CIRM regulations, were not created with the intent of dictating how stem cell research should be done within the state, but rather, with the intent to outline what stem cell research projects CIRM would and would not fund.
- Contrary to the NAS guidelines, the proposed CIRM regulations were additionally designed to address all stem cell research rather than just embryonic stem cell research.
- The proposed CIRM regulations were similar to the NAS guidelines in that both specifically prohibit reproductive cloning, the culture of in-vitro embryos after a specified time limit (CIRM 12 days, NAS 14 days) the introduction of human stem cell lines into embryos of non-human primates, the introduction of stem cells from any species into a human embryo, and the breeding of any animal into which a human stem cell line has been introduced. The proposed CIRM regulations additionally follow the recommendations of the NAS guidelines by mandating research oversight from a SCRO committee, identical to the ESCRO committee, but not limited to embryonic stem cell research.

Professor Charo continued stating the proposed CIRM regulations specifically require:

- Justification to derive new cell lines as well as minimum requirements that must be met for institutions wishing to work with existing or out of state cell lines including: (1) the donors gave voluntary and informed consent, (2) there was no payment for the original tissue and (3) the donation was taken under the supervision of an IRB or its equivalent.
- Reimbursement to women for the cost of any medical care that is a direct and proximal result of oocyte donation.

- Offering donors the opportunity to register their preferences for future use of any resultant stem cell lines derived from their donated tissue.
- Specific risk information be provided to oocyte donors.
- Designation of who is required to give consent for cord blood.
- The creation of a central repository of information so that organizations are aware of the research that is being conducted within their institution.

Professor Charo reported that SCRO committees and IRBs may in fact share many of the same members. She also offered that a potential avenue to improve compatibility between the CDHS and CIRM standards may be for SCRO Committees to report their findings directly to the IRBs so that the IRBs are then able to comply with the legal requirements of State law that governs non-CIRM funded research.

**Agenda Item # 7: Committee Discussion of NAS Guidelines and CIRM Regulations**

The committee members discussed concerns that the guidelines and regulations do not address obtaining oocytes by alternative methods. There was also discussion about the meaning of the CIRM regulations on oocyte donation not compromising the optimal reproductive success of a woman. Dr. Geoffrey Lomax, Senior Officer from CIRM, explained that the provision for this in the proposed CIRM regulations was referring to the management of the donated egg, i.e. preventing donated eggs from being used for research prior to a woman's or a couple's ability to reach their fertility goals. Members also discussed the requirement that the donor must have voluntarily consented to donate their tissue without receiving valuable consideration for their donation.

**Agenda Item # 10: Presentation: Gaps in NAS and CIRM Standards (David Magnus, Ph.D)**

Dr. Magnus began his presentation by discussing the flexibility offered in creating guidelines rather than regulations and listed the ways the guidelines created by SB 322 might fill in any gaps left by the proposed CIRM regulations and the NAS guidelines. His recommendations included the following:

1) Recognizing 'research donor' as unique from 'research subject' or 'patient'.
2) Clarifying the meaning of de-identification of research donors or subjects verses anonymization.
3) Advising on the method and need for 're-contacting' patients or donors.
4) Advising on patient confidentiality issues.
5) Avoiding the accidental destruction of embryos stored for future use.
6) Avoiding the term and propagating the misconception of 'therapeutic cloning'.
7) Avoiding the therapeutic misconception in informed consent processes.
8) Advising on requirements for clinical trials.

To view Dr. Magnus' presentation, see this URL:
http://www.mch.dhs.ca.gov/documents/ppt/DrMagnus_Stem_Cell_Guidelines_Presentation_2-24-06.ppt

**Agenda Item #11: Committee Discussion of Areas that Need Development of New and/or Modified Guidelines**

The Committee elected that the Chair and the Vice-Chair, consulting when necessary with other members of the panel, would devise subcommittees around subjects that would be relevant for the next agenda. Subcommittee members would research and gather information around these identified areas and then lead a discussion at the next HSCR Advisory Committee meeting.

**Agenda Item #12: Public Comment**

Charis Thompson, from Berkeley, discussed several concerns as well as offered suggestions to consider when discussing oocyte donation and ovarian hyperstimulation. These included:

1. The importance of timing of informed consent during treatment for women undergoing ovarian hyperstimulation and egg donation when the fertility outcome is known verses when it is unknown (i.e. the donor is finished having children or does not want children vs. the donor has not yet had children or may in the future want to have children).

2. The possibility of allowing women to accept payment for oocyte donations to IVF clinics for all of their eggs or a portion of their eggs up to 10 for example, and then any eggs over that number could be donated without payment to research.
3. The three main concerns around the long-term effects of oocyte donation:
    a. The unknown effect on fertility.
    b. The effects on children born after ovarian hyperstimulation.
    c. Ovarian cancer.
4. A scientific goal should be to pursue in vitro maturation of immature oocytes and ovarian sectioning.
5. Addressing public concern about the unknown effects of medical treatments derived from stem cells.
6. Addressing minority communities concerns that stem cell researchers will not sample eggs and embryos from diverse communities to ensure adequate representation.

Shannon Smith-Crowley, a lobbyist representing the American College of OB-GYNs and the American Society for Reproductive Medicine discussed concerns in the proposed CIRM regulations about oocyte donation. Her respective organizations:

1. Overall support the proposed CIRM regulations, but would like to see payment to women for their time and effort in oocyte donation added to them. She reported that the American Society for Reproductive Medicine has guidelines on how to compensate women for oocyte donation without providing an undue incentive to participate.
2. Disagree with the proposed CIRM regulation on informed consent that stipulates a donor must receive an adequate period of deliberation prior to making a decision about donation.

**Agenda Item # 13: Next Meeting**

In order to ensure the subcommittees had enough time to meet and discuss their topics, it was decided that the next HSCR Advisory Committee meeting would be held in either May or June.

The committee approved the motion to thank the Children's Hospital of Oakland Research Institute, its Director and staff for their hospitality and their beautiful facility.

The committee elected to adjourn the meeting.